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## IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

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KAZUHIKO KATOU, ET AL.

: EXAMINER: WELTER, RACHEL E.

SERIAL NO: 10/589,658

.

FILED: AUGUST 16, 2006

GROUP ART UNIT: 1611

FOR: TOOTHPASTE COMPOSITION

58:

## DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Kazuhiko KATO who deposes and states:

- 1. That I am a graduate of Ibaraki University and received a Master's degree in the year 1992.
- 2. That I have been employed by Kao Corporation, for 20 years and I have been involved in research and development of oral products for 17 years from 1995 to present.
- 3. That I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.
- 4. That the following experiments were carried out by me or under my direct supervision and control.
- 5. The toothpastes were prepared according to the composition shown in the Table below. The content of sugar alcohol (*i.e.*, erythritol, sorbitol, or both) and water was normalized for each example and comparative example to accurately control against the effects of increasing or decreasing sugar alcohol content. The cooling sensation, storage stability, and shape retention/feeling upon use were evaluated for toothpaste compositions having different ratios of water and erythritol.

6. The cooling property of the toothpastes was evaluated as compared with the reference composition based on the criteria and in a manner similar to the examples described by paragraph [0031] of the present specification. The reference toothpaste (last col. in the table below) is not a comparative example since it does not contain the same amount of sugar alcohol as the examples and comparative examples. It is provided only as a referent for measuring cooling sensation.

A: Obviously superior in refreshing feeling to the reference toothpaste

B: A little superior to in refreshing feeing to the reference toothpaste

C: Comparable in refreshing feeling to the reference toothpaste

7. The stability of each toothpaste was evaluated by filling the toothpaste in a toothpaste tube, storing it at 50°C for two weeks, after that cutting through and evaluating whether the liquid component was separated from the toothpaste or not based on the criteria described by paragraph [0032] of the present specification.

A: Separation of a liquid component is not observed

B: Separation of a liquid component is observed slightly

C: Separation of a liquid component is observed obviously

8. The shape retention and feeling of use of each toothpaste was evaluated by squeezing the toothpaste from the toothpaste tube having the diameter of 6 mm on a toothbrush in a length of about 1 cm and evaluating the state of the toothpaste based on the criteria described below.

Very good: Shape after the toothpaste is squeezed out on the toothbrush is

maintained and the toothpaste is not too hard or too soft.

Good: Shape after the toothpaste is squeezed out on the toothbrush is

maintained and the toothpaste does not sag from the toothpaste

although the toothpaste is soft.

Bad: The toothpaste sags from the toothbrush and cannot maintain its

shape.

Hard: The toothpaste is hard and is difficultly squeezed out from the tube.

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9. Comparison Table

| ,            |  |            |       | <del></del> i | · · · · · · |                            | ·           |              |                   |                 |     |            | <del> </del>                  | 1 1          | · · · · · · · · · · · · · · · · · · ·  |                   | r                 | <del>,                                    </del> |
|--------------|--|------------|-------|---------------|-------------|----------------------------|-------------|--------------|-------------------|-----------------|-----|------------|-------------------------------|--------------|--|-------------------|-------------------|--|
|              | Ref.   | 0          | 20    | 40            | 21.75       | 0                          | 0.5         | 0.05         | 1.5               | 10              | 5   | 1.2        | 41.75                         | 100          |  | ပ                 | 1                 |  |
| Comparatives | Comp.<br>Ex. S   | 0          | 30    | 0             | 64.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   |            | 94.5                          | 100          | Ŋ  | Y                 | C                 | Bad  |
|              | Comp.<br>Ex.12   | 64.5       | 30    | 0             | 0           | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | Ą                 | C                 | PooD   |
|              | Comp.<br>Ex.11   | 59.5       | 35    | 0             | 0           | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   |            | 94.5                          | 100          | Yes  | Ą                 | В                 | Bad  |
|              | Comp.<br>Ex.10   | 35         | 35    | 0             | 24.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   |            | 94.5                          | 100          | No   | ပ                 | Ą                 | Good   |
|              | Comp.<br>Ex.9  | 30         | 30    | 0             | 34.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | - Internet | 94.5                          | 100          | No   | Ü                 | А                 | Good   |
|              | Comp.<br>Ex.8  | 24         | 15    | 0             | 55.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   |            | 94.5                          | 100          | No   | C                 | Д                 | Good   |
|              | Comp.<br>Ex.7  | 30         | 10    | 0             | 54.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | Ą                 | U                 | Good   |
|              | Comp.<br>Ex.6  | 09         | 10    | 0             | 24.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | Ą                 | ပ                 | Hard   |
|              | Comp.<br>Ex.5  | 65         | 15    | 0             | 14.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | A                 | ט                 | Hard   |
| Invention    | Ex. F  | 09         | 30    | 0             | 4.5         | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | Ţ          | 94.5                          | 100          | Yes  | Ą                 | В                 | Good   |
|              | Ex. E  | 35         | 30    | 0             | 29.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | В                 | ¥                 | Very<br>good                                     |
|              | Ex. C  | 30         | 15    | 0             | 49.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | 1          | 94.5                          | 100          | Yes  | A                 | В                 | Good   |
|              | Ex. B  | 09         | 15    | 0             | 19.5        | 1.2                        | 0.05        | 0.05         | 1.2               | 0               | 2   | -          | 94.5                          | 100          | Yes  | A                 | В                 | Good   |
|              | The second secon | Erythritol | Water | Glycerin      | Sorbitol    | Na-Carboxymethyl-cellulose | Xanthan gum | Na-Saccharin | Na-lauryl sulfate | Abrasive silica | PEG | Flavor     | Erythritol + sorbitol + water | Total amount | Meets Equation 1?<br>(wt% of water) $x$<br>$0.3 + 2.5 \le (wt\%)$ of erythritol) | Cooling sensation | Storage stability | Shape retention-<br>feeling upon use             |

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- 10. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
  - 11. Further deponent saith not.

Nazuhiko Katou
Signature:

March 23, 20/2
Date